IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHER DISTRICT OF TEXAS
DALLAS DIVISION

CINDY BURTON,	§	
Plaintiff,	§	
	§	
v.	§	CIVIL ACTION NO.
	§	3:99–CV:0305–G
	§	
WYETH-AYERST LABORATORIES	§	
DIVISION OF AMERICAN HOME	§	ECF
PRODUCTS CORPORATION, ET AL.,	§	
Defendants.	§	

PLAINTIFF'S BRIEF IN SUPPORT OF RESPONSE TO DEFENDANT WYETH'S MOTION TO LIMIT THE TESTIMONY OF PLAINTIFF'S GENERIC EXPERTS

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Plaintiff, Cindy Burton, files this brief in support of her response to Wyeth's motion on generic experts, as follows:

I. Introduction

Wyeth's motion, for the most part, goes through the MDL orders and recites what the MDL court held on *Daubert* rulings with regard to the Generic Experts. Plaintiff intends to follow all *Daubert* rulings of the MDL court. Thus, Wyeth's motion is unnecessary and should be denied.

II. Plaintiff Will Not Call This Generic Expert

Plaintiff will not call Dr. Oury as an expert witness.

III. Argument

A. These Matters Have Already Been Ruled Upon By The MDL Judge And There Is No Reason To Revisit Them

The MDL court expended a great deal of time and resources "disposing of *Daubert* issues applicable to the vast majority of cases within this MDL No. 1203." *See In re: Diet Drugs*, Civil Action No. 99-20593, MDL Docket No. 1203 (E.D. Pa. February 1, 2001), Memorandum and Pretrial Order No. 1685, at 2, attached as Exhibit 5.[1] These *Daubert* rulings were to have "final and uniform value" in the vast majority of cases. *Id.* at 5.

Plaintiff intends to rely on the *Daubert* rulings of the MDL court, just as other courts have done. *See Smith v. Wyeth-Ayerst Laboratories Co.*, 278 F.Supp. 684, 701 (W.D. N.C. 2003) ("The Court intends to follow the MDL ruling."). Thus, Wyeth's motion is unnecessary. However, in this response, Plaintiff will address Wyeth's arguments and identify what the MDL court held.

B. Dr. Avorn

Wyeth asks that this Court exclude Dr. Avorn's testimony: (1) regarding the thoughts and expectations of physicians; (2) "reaction" to documents discussing the approval process for Redux; (3) speculation concerning the processing of adverse drug event reports; and (4) recounting of various documents or testimony.

Plaintiff will not call Dr. Avorn to testify on what doctors expect or FDA regulations.

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[1] References are to Exhibits in the Appendix of Exhibits for Plaintiff's Responses to Wyeth's January 2, 2007 Motions. The Appendix contains all the evidence to respond to all the motions.

However, the MDL court held that Dr. Avorn is "fully qualified within [his] discipline [ ] and that [he] can testify concerning the risks and benefits of the diet drugs in issue." *See In re: Diet Drugs*, Civil Action No. 99-20593, MDL Docket No. 1203 (E.D. Pa. June 20, 2000), Memorandum and Pretrial Order No. 1332, at 9, attached as Exhibit 22. Further, the parties agreed that Dr. Avorn "can provide the medical and scientific testimony as it relates to PPH." *Id.*

The MDL court also held that while Dr. Avorn was not qualified to testify about FDA regulation, Dr. Avorn is "fully qualified to opine on the medical facts and science regarding the risks and benefits of the diet drugs in question and to compare that knowledge with what was provided in the text of labeling and warnings in the diet drugs in question. In other words, [Dr.] Avorn [is] fully qualified to render an opinion as to the label's completeness, accuracy and – it follows from that – the extent to which the inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits of the diet drugs in issue are or were at the time the labeling was published." *Id.* The MDL court held that it could not exclude Dr. Avorn's opinions "comparing the facts in evidence with the status of the content shown in the labeling of the diet drugs." *Id.*

With regard to documents, the MDL court held as follows: "Whether a particular document can be introduced through a witness as a basis for his expert opinion will, of course, be left to the trial judge in the transferor court." *Id.* at 7; *see also First Nat. Bank of Louisville v. Lustig*, 96 F.3d 1554, 1576 (5th Cir. 1996) (expert may rely on hearsay evidence in forming an opinion). The MDL court further held that if the document is admitted in

evidence, it can be read or paraphrased to a witness but, on the other hand, if it is inadmissible, irrelevant or prejudicial, "it will not get into evidence and the witness will not be called upon to speak about it." *See* Exhibit 22, at 7. Because the MDL court could not predict whether the documents would be admissible at trial, the MDL court denied Wyeth's motion to exclude all testimony about documents. *Id.*

C. Drs. Barst and Rich

Wyeth argues that Drs. Barst and Rich should not be permitted to testify concerning: (1) FDA regulatory matters; (2) the efficacy of Pondimin and Redux for treating obesity; and (3) concerning Aminorex.

Plaintiffs will not ask Dr. Barst or Rich to testify about FDA regulatory matters, except "to the extent that Dr. Rich testifies as to regulatory matters and occurrences of which he has firsthand personal knowledge, such as his participation in FDA advisory committee hearings . . ." *See* Exhibit 5, MDL Order 1685, at 55 n.22.[2] The MDL court held that Drs. Barst and Rich were fully competent, however, to testify as to the Wyeth label's "accuracy and the extent to which an inaccuracy or omission could either deprive or mislead a reader as to the risks of these diet drugs at the time the labeling was published." *Id.* at 56. Further, Drs. Barst and Rich can testify about the "origins, symptoms, treatment and other aspects of PH and PPH, including causation of these diseases by diet drugs." *Id.* at 54.

[2] Dr. Rich has been designated as a fact witness by the Plaintiff.

Plaintiffs will not ask Drs. Barst or Rich to testify as to the efficacy of Pondimin or Redux for treating obesity (the MDL court held that Dr. Sears, the creator of the Zone Diet, was fully competent to speak to that issue).

With regard to testimony regarding the Aminorex experience in the 1960s, the MDL court held that such evidence "may support evidence of notice to the pharmaceutical community . . ." *See* Exhibit 22, MDL Order 1332, at 9. Without hearing this evidence in context, the court cannot rule on its admissibility. *See Smith v. Wyeth-Ayerst Laboratories Co.*, 278 F.Supp.2d 684, 704 (W.D. N.C. 2003) (admitting Aminorex evidence for notice, historical data).

D. Dr. Bloor

Wyeth contends that Dr. Bloor's testimony was excluded in the MDL court so it should be excluded here. Wyeth is partially correct. Dr. Bloor's testimony concerning rat slides was inadmissible because it could not be tested, and his testimony on causation was excluded. *See* Exhibit 5, MDL Order 1685, at 39-43. However, the MDL court held that Dr. Bloor could testify that with regard to whether a study "warranted further investigation with regard to the potential of fenfluramines to cause cardiac fibrosis." *Id.* at 44.

E. Dr. Gueriguian

Wyeth contends Dr. Gueriguian cannot testify about: (1) the prescribing practices of other physicians; (2) his personal opinions about corporate conduct; and (3) pathology testimony based on unreliable methodology. Wyeth contends that such testimony was excluded by the MDL. Again, Wyeth is partially correct.

Plaintiff does not intend to call Dr. Gueriguian to testify about the prescribing practices of other physicians. And, Plaintiff does not intend to ask for Dr. Gueriguian's testimony based on Dr. Bloor's unreliable testimony or Dr. Gueriguian's testimony concerning Wyeth's corporate intent.

However, Dr. Gueriguian was the Medical Director at the FDA during the relevant time period. Plaintiff intends to call him to testify—and the MDL court ruled he could—about how information should be communicated to the FDA, what information should be reflected on labels as mandated by applicable regulations, and what reasonable FDA officials would do with adverse event information. *Id.* at 51-54.

F. Dr. Hayes

Dr. Hayes is the former commissioner of the FDA. Although he was not addressed by the MDL court[3], Wyeth seeks to exclude his testimony as to: (1) Wyeth's motives and intent; (2) recitation of contents of various documents; and (3) use of "non-regulatory meaning of certain terminology in a regulatory context."

Plaintiff does not intend to call Dr. Hayes to testify concerning the corporate intent of Wyeth. With regard to documents, as the MDL court observed, if the documents are admitted or admissible, Dr. Hayes can read from them. *See* Exhibit 22, MDL Order 1332, at 7. That can only be determined at trial.

With regard to "non-regulatory terminology," it appears that Wyeth is attempting to argue that Dr. Hayes uses the term "medically serious" incorrectly. It appears that Wyeth is

[3] The MDL court denied a motion to exclude Dr. Hayes. *See* Exhibit 5, MDL Order 1685, at 33 n.9.

arguing that this Court should exclude such evidence because it is unreliable or that it may tend to confuse jurors under FED. R. EVID. 403. Obviously, such a challenge should be made at trial when the court has the opportunity to understand the alleged error in context.[4] More properly, the matter appears one for cross-examination. *See Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. 579, 596 (1993).

G. Dr. Sears

Finally, Wyeth seeks to exclude the testimony of Dr. Barry Sears on: (1) FDA efficacy requirements; or (2) Wyeth's marketing or disclosure obligations. Plaintiff does not intend to call Dr. Sears to testify about the FDA requirements or about Wyeth's marketing or disclosure obligations. However, as the MDL court held, Dr. Barry Sears, the creator of the Zone Diet, is fully qualified under *Daubert* to testify "about the effectiveness of Pondimin and Redux in treating obesity." *See* Exhibit 5, MDL Order 1685, at 64.

CONCLUSION

Plaintiff, Cindy Burton, intends to follow the MDL's *Daubert* rulings to the letter. For that reason, Wyeth's motion is unnecessary and should be denied.

[4] For example, Wyeth's motion asserts, without evidence other than citations to the Code of Federal Regulation, that Dr. Hayes, the former Commissioner of the FDA is using the term "medically serious" incorrectly, that is, not as it is used in the cited statutes. In the full context of the question answered in the definition, Dr. Hayes was asked, without objection, if there were adverse event reports that he considered medically serious. *See* Wyeth Motion, at App. 7, pp. 89-91. What he considers medically serious may be different than what the statute calls "serious." Without further elaboration, this Court could not decide how to rule.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 8, 2007, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, Northern District of Texas, using the electronic case files system of the court. The electronic case files system sent a "Notice of Electronic Filing" to the following individuals:

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